

United States Government

Department of Energy

# memorandum

Carlsbad Field Office  
Carlsbad, New Mexico 88221

DATE: August 28, 2003

REPLY TO  
ATTN OF: CBFO:QA:MN:GS:03-2550:UFC 2300.00

SUBJECT: Issuance of Corrective Action Reports Initiated During Audit A-03-05

TO: Brian Edgerton, DOE-ID  
Richard Cullison, DOE-ID

The Carlsbad Field Office (CBFO) performed Audit A-03-05 of the Idaho National Environmental and Engineering Laboratory (INEEL) Advanced Mixed Waste Treatment Project (AMWTP) on August 18 - 22, 2003. CBFO Corrective Action Reports (CARs) 03-072, 03-073, 03-74, 03-075, 03-076, and 03-077 are attached.

Please document on the attached CAR continuation sheets your proposed corrective actions and a schedule for completion of CARs 03-072, 03-073, and 03-074 and forward to me prior to the response due date identified in CAR block 14. Also attached are the instructions for providing corrective action responses for your use in preparing the required responses.

Please provide the expected completion dates of the corrective actions for CARs 03-075, 03-076, and 03-077 by the response due date identified in CAR block 14 in order that a closeout visit can be planned and scheduled.

If you have any questions or comments, please contact me at (505) 234 -7483.

Martin P. Navarrete  
Quality Assurance Specialist

Attachments

030835



Edgerton/Cullison

-2-

August 28, 2003

cc: w/attachments

A. Holland, CBFO \*ED

K. Watson, CBFO \*ED

R. Knerr, CBFO \*ED

E. Schweinsberg, BNFL \*ED

J. Wells, DOE-ID \*ED

E. Dumas, BNFL \*ED

M. Eagle, EPA \*ED

E. Feltcorn, EPA \*ED

R. Joglekar, EPA \*ED

S. Zappe, NMED \*ED

S. Holmes, NMED \*ED

S. Webb, EEG \*ED

D. Winter, DNFSB \*ED

J. May, CTAC \*ED

A. Pangle, CTAC \*ED

K. Dunbar, WRES

CBFO QA File

CBFO M&RC

# CORRECTIVE ACTION REPORT

1. CAR No.: 03-072	2. Activity Report No.: A-03-05	3. Page <u>1</u> of <u>3</u>
4. Controlling Document: MP-TRUW-8.8 Section 4.1, MP-TRUW-8.9, Section 1.1, & 1.2		5. CBFO Assessment Team Leader: <del>A. Holland</del> <b>M. P. NAVARRETE</b> <b>8-28-03</b>
6. Responsible Organization: AMWTP		7. CAQ Was Discussed With: Eric Schweinsberg, Elvin Dumas
8. Requirement that was violated: See continuation sheet		
9. Condition Adverse to Quality:  AMWTP did not ensure that the batch data reports (BDRs) were complete. (See continuation sheet)		
10. Suggested Actions (Optional):		
11a. Significant CAQ (Yes or No): Yes		
11b. Work Suspension Recommended (Yes or No): No		
11c. RCRA-Related (Yes or No): Yes		
11d. Accelerated Corrective Action Required (Yes or No): No		
12. Types of Actions: Remedial: <u>X</u> Investigative: <u>X</u> Root Cause: <u>X</u> Actions to Preclude Recurrence: <u>X</u>		
13. CAR Initiator <u>David H. Price</u> <i>David H. Price</i> Date: <u>8/26/03</u>		
14. Response Due Date: <u>9/30/2003</u> Corrective Action Plan Required: <u>Yes</u> Required Corrective Action Completion Date: <u>N/A</u>		
15. a. Concurrence: <i>M. P. Navarrete</i> <b>8-28-03</b> Assessment Team Leader Date b. <u>N/A</u> Responsible Assistant Manager Date c. <i>David H. Price</i> <b>8/28/03</b> Quality Assurance Manager Date		
16. Corrective Actions Proposed by the Responsible Organization: Use CAR Continuation Sheet		
17. Acceptance of Proposed Corrective Actions:  Assessment Team Leader Date		
18. Verification of Corrective Action Completion: (Use CAR Continuation Sheet)		
19a. Verified By: _____ Name Date		
19b. Trend Cause Code: _____		
20. Closure: _____ Quality Assurance Manager Date		

# CBFO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: 03-072

2. Activity No.: A-03-05

3. Page 2 of 3

**Block #8 : Requirement that was violated:**

WIPP WAP Section B3-10b (2) states:

"The Site Project Manager Review is the final validation that all of the data contained in Batch Data Reports have been properly reviewed as evidenced by signature release and completed checklists. One hundred percent of the Batch Data Reports must have Site Project Manager signature release. The Site Project Manager signature release must occur as soon as practicably possible after the Site Project QA officer signature release in order to determine and correct negative quality trends in the sampling or analytical process. However at a minimum, the Site Project Manager signature release must be performed before any waste associated with the data reviewed is managed, stored, or disposed at WIPP. This signature release must ensure the following:  
The Site Project Manager or designee shall determine the validity of the drum age criteria (DAC) assignment made at the data generation level based upon an assessment of the data collection and evaluation necessary to make the assignment. Data generation level independent technical, technical supervisory, and QA officer (or designee) review, validation, and verification have been performed as evidenced by the completed review checklists and appropriate signature releases. Batch data review checklists are complete. Batch Data Reports are complete and data are properly reported (e.g., data are reported in the correct units, with the correct number of significant figures, and with qualifying flags). Verify that data are within established data assessment criteria and meet all applicable QAOs (Section B3-11)."

WIPP WAP Section B3-10b (1) states:

"The Site Project QA Officer review ensures that the Batch Data Reports received from the data generation level is complete, validates and verifies that the QC checks were done properly and meet program criteria, and ensures that the QAOs have been met. One hundred percent of the Batch Data Reports must receive Site Project QA Officer signature release. The Site Project QA Officer signature release must occur as soon as practicably possible in order to determine and correct negative quality trends in the sampling or analytical process. However at a minimum, the Site Project QA Officer signature release must be performed before any waste associated with the data reviewed is managed, stored, or disposed at WIPP. This signature release must ensure the following:

Batch Data Reports are complete and data are properly reported (i.e., data are reported in correct units, with correct significant figures, and with correct qualifying flags). Sampling batch QC checks (e.g., equipment blanks, field duplicates, field reference standards) were properly performed, and meet the established QAOs and are within established data usability criteria. Testing batch QC checks (e.g., replicate scans, measurement system checks) were properly performed. Radiography data are complete and acceptable based on evidence of videotape review of one waste container per day or once per testing batch, whichever is less frequent, as specified in B1-3b (2). Analytical batch QC checks (e.g., laboratory duplicates, laboratory blanks, matrix spikes, matrix spike duplicates, laboratory control samples) were properly performed and meet the established QAOs and are within established data usability criteria. On-line batch QC checks (e.g., field blanks, on-line blanks, on-line duplicates, on-line control samples) were properly performed and meet the established QAOs and are within established data usability criteria. Proper procedures were followed to ensure representative samples of headspace gas and homogenous solids and soil/gravel were taken."

MP-TRUW-8.8 Section 4.1.1 states:

"The ITR ensures by review of the raw data that data generation and reduction are technically correct; calculations are verified correct; deviations are documented and QA/QC results are complete, documented correctly, and compared against appropriate criteria."

MP-TRUW-8.8 Section 4.1.3 states:

"The TS review ensures that the ITR was performed completely, that the Batch Data Report is complete, and verifies that the results are technically reasonable."

MP-TRUW-8.8 Section 4.1.4 states:

"The DGL QA review ensures that the Batch Data Report is complete, that QC checks meet the acceptance criteria, and that the appropriate QAOs have been met."

MP-TRUW-8.9, Section 1.1 states:

"The SQAO review ensures that the Batch Data Report received from the data generation is complete, validates, and verifies that the QA checks were done properly and ensures that the QAOs have been made."

# CBFO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: 03-072

2. Activity No.: A-03-05

3. Page 3 of 3

Block #8: Requirement that was violated:

MP-TRUW-8.9, Section 1.2 states:

"The SPM Review is the final validation that all of the data contained in Batch Data Reports have been properly reviewed as evidenced by signature release and completed checklist."

"The reviews act as the complete data validation summary."

Block # 9 : Condition Adverse to Quality (continued)

BDRs were printed from the AMWTP Waste Tracking System (WTS). The BDRs were incomplete, due to the fact that some data fields had information truncated during the printing process. AMWTP personnel performed data generation and project level validation and verification. The Site Project QA Officer and the Site Project Manager signed checklist and individual pages that constitute the record copies within the BDR. This action resulted in AMWTP approving and authenticating incomplete quality records

# CORRECTIVE ACTION REPORT

1. CAR No.: 03-073	2. Activity Report No.: A-03-05	3. Page <u>1</u> of <u>2</u>
4. Controlling Document: INST-OI-13, Rev. 13		5. CBFO Assessment Team Leader: <u>A. Holland</u> <span style="float: right;">8-28-03</span> <u>M.P. NAWARRE</u>
6. Responsible Organization: AMWTP		7. CAQ Was Discussed With: Charles Colby, Jesse Melton
<p>8. Requirement that was violated:  INST-OI-13, Rev. 13, Section 4.1.4.1 states that "...internal standards are added to every analysis to serve as surrogates..." and Section 4.13.1 states "Internal standards (ISTDs) are introduced into the GC system at the injection port...The ISTDs have a 70% to 130% Recovery Limit and a Retention Time Limit of <math>\pm 0.4</math> minutes."</p>		
<p>9. Condition Adverse to Quality:  AMWTP did not monitor ISTDs (used as surrogates) retention times or recoveries in violation of procedure INST-OI-13.</p>		
10. Suggested Actions (Optional): None		
11a. Significant CAQ (Yes or No): No 11b. Work Suspension Recommended (Yes or No): No 11c. RCRA-Related (Yes or No): Yes 11d. Accelerated Corrective Action Required (Yes or No): No		
12. Types of Actions: Remedial: <u>X</u> Investigative: <u>X</u> Root Cause: <u>X</u> Actions to Preclude Recurrence: <u>X</u>		
13. CAR Initiator: <u>N. Frank/B.J. Verret</u> <span style="float: right;">Date: <u>8/25/03</u></span>		
14. Response Due Date: <u>9/30/03</u> Corrective Action Plan Required: <u>Yes</u> Required Corrective Action Completion Date: <u>N/A</u>		
15. a. Concurrence: <u>M.P. NAWARRE</u> <span style="float: right;"><u>8-28-03</u></span> Assessment Team Leader Date Responsible Assistant Manager Date c. <u>N/A</u> Quality Assurance Manager Date		
16. Corrective Actions Proposed by the Responsible Organization: Use CAR Continuation Sheet		
17. Acceptance of Proposed Corrective Actions: Assessment Team Leader Date		
18. Verification of Corrective Action Completion: (Use CAR Continuation Sheet)		
19a. Verified By: _____ Name Date		
19b. Trend Cause Code: _____		
20. Closure: _____ Quality Assurance Manager Date		

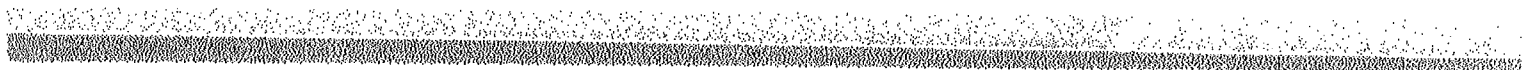
# CBFO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: 03-073

2. Activity No.: A-03-05

3. Page 2 of 2



# CORRECTIVE ACTION REPORT

1. CAR No.: 03-074		2. Activity Report No.: A-03-05		3. Page <u>1</u> of <u>2</u>	
4. Controlling Document: INST-01-12			5. CBFO Assessment Team Leader: <u>A. Holland</u>		
6. Responsible Organization: A			7. CAQ Was Discussed With: <u>Gina Tedford</u>		
8. Requirement that was violated: INST-01-12, Section 4.7.3.3.8, Note 2 "Not all items found in waste containers are addressed by this instruction. Any items found that are not listed in the Waste Material Item List shall be identified and documented using best judgment of the OT. This shall be documented in the comments section of the WTS screen."					
9. Condition Adverse to Quality: AMWTP is not recording an inventory of waste items in the comment section of the WTS RTR screen as required by INST-01-12.					
10. Suggested Actions (Optional):					
11a. Significant CAQ (Yes or No): No					
11b. Work Suspension Recommended (Yes or No): No					
11c. RCRA-Related (Yes or No): Yes					
11d. Accelerated Corrective Action Required (Yes or No): No					
12. Types of Actions: Remedial: <u>X</u> Investigative: <u>X</u> Root Cause: <u>X</u> Actions to Preclude Recurrence: <u>X</u>					
13. CAR Initiator: <u>Thomas Putnam</u> <u>Thomas S. Putnam</u> Date: <u>8/25/03</u>					
14. Response Due Date: <u>9/30/03</u> Corrective Action Plan Required: Yes					
Required Corrective Action Completion Date: <u>N/A</u>					
15. a. Concurrence: <u>M.P. Narasimhan</u> <u>8-28-03</u> b. <u>N/A</u>					
Assessment Team Leader		Date		Responsible Assistant Manager	
c. <u>N/A</u>		Date		Date	
Quality Assurance Manager					
16. Corrective Actions Proposed by the Responsible Organization: Use CAR Continuation Sheet					
17. Acceptance of Proposed Corrective Actions:					
Assessment Team Leader		Date			
18. Verification of Corrective Action Completion: (Use CAR Continuation Sheet)					
19a. Verified By: _____					
Name		Date			
19b. Trend Cause Code: _____					
20. Closure: _____					
Quality Assurance Manager		Date			



# CBFO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: 03-074

2. Activity No.: A-03-05

3. Page 2 of 2

Block #

# CORRECTIVE ACTION REPORT

1. CAR No.: 03-075	2. Activity Report No.: A-03-05	3. Page <u>1</u> of <u>2</u>								
4. Controlling Document: MP-Q&SI-5.3, Rev. 1 and MP-Q&SI-5.4, Rev. 1		5. CBFO Assessment Team Leader: <u>MP-03-05</u> <u>WCH 8-28-03</u>								
6. Responsible Organization: AMWTP		7. CAQ Was Discussed With: Charles Colby, Jesse Melton								
<p>8. Requirement that was violated: MP-Q&amp;SI-5.3, Rev. 1, Section 1.0, Purpose/Scope states,</p> <p>"This procedure applies to all AMWTP personnel and subcontractors, and addresses:</p> <ul style="list-style-type: none"> <li>• Identification of a potential deficiency (failure, malfunction, deviation, violation of written requirements)"</li> </ul> <p>See Continuation Sheet for additional requirements.</p>										
<p>9. Condition Adverse to Quality: AMWTP failed to document a programmatic deficiency by issuing a corrective action report to address the failure of headspace gas operators to perform sections 4.12 and 4.13 of procedure INST-OI-13.</p> <p>See Continuation Sheet for details.</p>										
10. Suggested Actions (Optional): None										
<table style="width: 100%;"> <tr> <td>11a. Significant CAQ</td> <td>(Yes or No): No</td> </tr> <tr> <td>11b. Work Suspension Recommended</td> <td>(Yes or No): No</td> </tr> <tr> <td>11c. RCRA-Related</td> <td>(Yes or No): No</td> </tr> <tr> <td>11d. Accelerated Corrective Action Required</td> <td>(Yes or No): No</td> </tr> </table>			11a. Significant CAQ	(Yes or No): No	11b. Work Suspension Recommended	(Yes or No): No	11c. RCRA-Related	(Yes or No): No	11d. Accelerated Corrective Action Required	(Yes or No): No
11a. Significant CAQ	(Yes or No): No									
11b. Work Suspension Recommended	(Yes or No): No									
11c. RCRA-Related	(Yes or No): No									
11d. Accelerated Corrective Action Required	(Yes or No): No									
12. Types of Actions: Remedial: <u>X</u> Investigative: _____ Root Cause: _____ Actions to Preclude Recurrence: <u>X</u>										
13. CAR Initiator: <u>N. Frank/B.J. Verret</u> Date: <u>8/25/03</u>										
<p>14. Response Due Date: <u>9/30/03</u> Corrective Action Plan Required: No</p> <p>Required Corrective Action Completion Date: <u>N/A</u></p>										
<p>15. a. Concurrence: <u>MP-03-05</u> b. <u>N/A</u></p> <p style="text-align: center;">Assessment Team Leader                      Date                      Responsible Assistant Manager                      Date</p> <p>c. <u>N/A</u></p> <p style="text-align: center;">Quality Assurance Manager                      Date</p>										
16. Corrective Actions Proposed by the Responsible Organization: Use CAR Continuation Sheet										
17. Acceptance of Proposed Corrective Actions:										
<p>Assessment Team Leader _____ Date _____</p>										
18. Verification of Corrective Action Completion: (Use CAR Continuation Sheet)										
19a. Verified By: _____										
Name	Date									
19b. Trend Cause Code: _____										
20. Closure: _____										
Quality Assurance Manager	Date									

# CBFO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: 03-075

2. Activity No.: A-03-05

3. Page 2 of 2

## Block # 8 : Requirement that was violated (continued)

MP-Q&SI-5.3, Rev. 1, Section 4.1.2 states,

"In the event of an undesirable situation, a condition adverse to quality, or an unacceptable safety risk, the work shall be suspended until the appropriate procedure change provisions are implemented."

Procedure MP-Q&SI-5.4, Rev. 1, Section 5.3.1 states:

"The QA Manager or designee will review the NCR record to evaluate the following:

- Determine if a Corrective Action Report and formal Root Cause Analysis are required"

## Block # 9 : Condition Adverse to Quality (continued)

### Details:

AMWTP NCR 3369 was written to document the following deviations and a technical resolution was provided with justification to use the data "as is". The NCR did not address a programmatic solution such as revising the procedure, and a corrective action report was not issued to address the programmatic issue.

Procedure INST-OI-13 was not followed in the following areas when analyzing headspace gas batches.

- Retention time windows were not calculated per Section 4.12
- Surrogates were not monitored per Section 4.13

# CORRECTIVE ACTION REPORT

1. CAR No.: 03-076	2. Activity Report No.: A-03-05	3. Page <u>1</u> of <u>2</u>
4. Controlling Document: DOE/WIPP-02-3122	5. CBFO Assessment Team Leader: <u>Mr. Holland</u> <u>Mr. Nunnally</u>	
6. Responsible Organization: AK, AMWTP Site	7. CAQ Was Discussed With: Shiela Hailey, Betty Tolman, Carolyn Abbott	
<p>8. Requirement that was violated: WAC Section 3.3.1 States: "For any of the ten radionuclides whose presence can be substantiated from AK, direct measurement, computations, or a combination thereof, and whose measured data are determined to be below the lower limit of detection (LLD) for that radionuclide, the site shall report the character string "&lt;LLD" to the WWIS for the activity and mass of that radionuclide; otherwise a value of zero shall be reported."</p>		
<p>9. Condition Adverse to Quality:</p> <p>The AK record indicated that Cs/Sr was not expected in this waste stream (RFETS 1<sup>st</sup> and 2<sup>nd</sup> Stage Sludge), which results in a "zero" entry in WWIS. However, NDA identified CS-137 during assay. The AKE identified and resolved the AK discrepancy concerning the presence of Cs-137. However, there is no indication that this information was communicated to the WWIS Manager who should now enter the measured value or &lt;LLD.</p>		
10. Suggested Actions (Optional):		
<p>11a. Significant CAQ (Yes or No): No</p> <p>11b. Work Suspension Recommended (Yes or No): No</p> <p>11c. RCRA-Related (Yes or No): No</p> <p>11d. Accelerated Corrective Action Required (Yes or No): No</p>		
12. Types of Actions: Remedial: <u>X</u> Investigative: <u>    </u> Root Cause: <u>    </u> Actions to Preclude Recurrence: <u>X</u>		
13. CAR Initiator: <u>D. Blauvelt</u> <u>Dick Blauvelt</u> Date: <u>8/27/03</u>		
<p>14. Response Due Date: <u>9/30/03</u> Corrective Action Plan Required: <u>No</u></p> <p>Required Corrective Action Completion Date: <u>N/A</u></p>		
<p>15. a. Concurrence: <u>Mr. P. Nunnally</u> <u>8-28-03</u> b. <u>N/A</u></p> <p style="text-align: center;">Assessment Team Leader                      Date                      Responsible Assistant Manager                      Date</p> <p>c. <u>N/A</u></p> <p style="text-align: center;">Quality Assurance Manager                      Date</p>		
16. Corrective Actions Proposed by the Responsible Organization: Use CAR Continuation Sheet		
17. Acceptance of Proposed Corrective Actions:		
<p>_____ Assessment Team Leader                      Date</p>		
18. Verification of Corrective Action Completion: (Use CAR Continuation Sheet)		
19a. Verified By: _____ Name                      Date		
19b. Trend Cause Code: _____		
20. Closure: _____ Quality Assurance Manager                      Date		

# CBFO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: 03-076

2. Activity No.: A-03-05

3. Page 2 of 2

Block #\_

# CORRECTIVE ACTION REPORT

1. CAR No.: CAR 03-077	2. Activity Report No.: A-03-05	3. Page <u>1</u> of <u>2</u>
4. Controlling Document: MP-DOCS-18.2, Records Management	5. CBFO Assessment Team Leader: <u>A. Holland</u> <span style="float: right;">8-28-03</span>	
6. Responsible Organization: AMWTP Records Management	7. CAQ Was Discussed With: <u>Robin Eickman</u>	
<p>8. Requirement that was violated:</p> <p>AMWTP Management Procedure MP-DOCS-18.2, revision 3, <i>Records Management</i>, Section 4.3.2.2 requires that all completed records being transferred to the Records Management Center (RMC) be submitted with a completed AMWTP Records Transmittal (Form-1044) with the records.</p>		
<p>9. Condition Adverse to Quality:</p> <p>The following records packages submitted to the RMC were submitted to and accepted by the RMC without a "Records Transmittal" (Form-1044) attached: Form Packages 1007, 1046, 1089, 1090, 1183, 1184, 1212, 1218, 1249, 1274, 1292, 1308, 1309, 1310, 1348, 1354, 1355, 1356, 1368, 1369, 1370, 1371, 1374, and form package 1379.</p>		
10. Suggested Actions (Optional):		
<p>11a. Significant CAQ (Yes or No): No</p> <p>11b. Work Suspension Recommended (Yes or No): No</p> <p>11c. RCRA-Related (Yes or No): No</p> <p>11d. Accelerated Corrective action Required (Yes or No): No</p>		
12. Types of Actions: Remedial: <input checked="" type="checkbox"/> Investigative: <input type="checkbox"/> Root Cause: <input type="checkbox"/> Actions to Preclude Recurrence: <input checked="" type="checkbox"/>		
13. CAR Initiator: <u>John Gray</u> <span style="float: right;">Date: <u>08/25/03</u></span>		
<p>14. Response Due Date: <u>9/30/03</u> Corrective Action Plan Required: No</p> <p>Required Corrective Action Completion Date: <u>N/A</u></p>		
<p>15. a. Concurrence: <u>M.P. [Signature]</u> <u>8-28-03</u> b. <u>N/A</u></p> <p style="text-align: center;">Assessment Team Leader                      Date                      Responsible Assistant Manager                      Date</p> <p style="text-align: center;">c. <u>N/A</u></p> <p style="text-align: center;">Quality Assurance Manager                      Date</p>		
16. Corrective Actions Proposed by the Responsible Organization: Use CAR Continuation Sheet		
17. Acceptance of Proposed Corrective Actions:		
<p style="text-align: center;">_____ Assessment Team Leader                      Date</p>		
18. Verification of Corrective Action Completion: (Use CAR Continuation Sheet)		
<p>19a. Verified By: _____ Date _____</p> <p style="text-align: center;">Name                      Date</p>		
19b. Trend Cause Code: _____		
<p>20. Closure: _____</p> <p style="text-align: center;">Quality Assurance Manager                      Date</p>		

# CBFO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: 03-077

2. Activity No.: A-03-05

3. Page 2 of 2

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## INSTRUCTIONS FOR PROVIDING CORRECTIVE ACTION RESPONSE

WASTE ISOLATION PILOT PLANT  
U.S. DEPARTMENT OF ENERGY

Carlsbad Field Office

PAGE 1 OF 1

CAR NO: \_\_\_\_\_

### INSTRUCTIONS FOR COMPLETING A CORRECTIVE ACTION RESPONSE TO A CAR ADDRESSING A CONDITION ADVERSE TO QUALITY

You are requested to provide a corrective action in response to this corrective action report (CAR) by the due date identified in block 14 of the CAR. If this date cannot be met, provide a written request for extension to the assessment team leader (block 5). This request must include justification for the delay and must be provided prior to the due date.

The response shall address the corrective actions indicated in block 12. As appropriate, develop the response in accordance with the following sequence and format:

In order to develop the CAR response, perform an investigative action to determine the extent and impact of the deficiency and to identify the root cause. Next, determine the actions required to correct the adverse condition. The response shall include the following information, as appropriate to block 12.

1. Corrective action response for CAR #

A. **Remedial Action**-Describe actions required or taken to correct the specific conditions noted and any similar conditions identified during the investigations.

B. **Extent and Impact of the Deficiency**-Describe the investigative actions performed to determine the extent and impact of the condition and the results. This will include a determination of the acceptability of any data generated prior to resolution of the deficiency.

C. **Root Cause Determination**-Identify the root cause of the condition as determined through investigative action.

D. **Corrective Action to Preclude Recurrence**-Identify the actions required to address the root cause of the condition in order to preclude recurrence.

2. For each action above, identify the individual assigned responsibility for completion of the action and the anticipated (or actual, if complete) completion date.

3. The response must identify the individual having the overall responsibility for completion of the corrective actions.



# CBFO CORRECTIVE ACTION REPORT

(Continuation Sheet)

1. CAR No.	2. Activity Report No	3. Page      Of